MEDICARE COVERAGE ISSUES MANUAL

Part 60 -- Durable Medical Equipment & Prosthetic Devices

60-22 VAGUS NERVE STIMULATION FOR TREATMENT OF SEIZURES

In the past 10 years, there have been significant advances in surgical treatment for epilepsy and in medical treatment of epilepsy with newly developed and approved medications. Despite these advances, 25-50 percent of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs.

The vagus nerve is a mixed nerve carrying both somatic and visceral afferent and efferent signals. The majority of vagal nerve fibers are visceral afferents with wide distribution. The basic premise of vagus nerve stimulation in the treatment of epilepsy is that vagal visceral afferents have a diffuse central nervous system projection and the activation of these pathways has a widespread effect upon neuronal excitability. Besides activation of well-defined reflexes, vagal stimulation produces evoked potentials recorded from the cerebral cortex, the hippocampus, the thalamus, and the cerebellum.

The vagus nerve stimulation system is comprised of an implantable pulse generator and lead and an external programming system used to change stimulation settings. Clinical evidence has shown that vagus nerve stimulation is safe and effective treatment for patients with medically refractory partial onset seizures, for whom surgery is not recommended or for whom surgery has failed.

Vagus nerve stimulation is not covered for patients with other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed.

A partial onset seizure has a focal onset in one area of the brain and may or may not involve a loss of motor control or alteration of consciousness. Partial onset seizures may be simple, complex, or complex partial seizures, secondarily generalized.